DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

FEB 2 5 2005

WARNING LETTER

VIA FEDERAL EXPRESS

Richard Meelia
CEO/President
Tyco Healthcare Group
15 Hamshire Street
Mansfield, Massachusetts 02048

Dear Richard Meelia:

During an inspection of your firm located in Tijuana B.C., Mexico on November 01, 2004, through November 05, 2004, our investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures a number of products at this facility, including the CapnoProbe SLS-1 Sublingual Sensor (CapnoProbe sensor). This product is a device under a United States law, the Federal Food, Drug, and Cosmetic Act (section 201(h) of the Act, (21 U.S.C. § 321(h)).

This inspection revealed that this device is adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. Significant violations include, but are not limited to, the following:

1. Failure to monitor and control process parameters and component and device characteristics during production, as required by 21 CFR 820.70(a)(2).

   For example, your firm did not monitor the bioburden of CapnoProbe sensor lots during production, after manufacturing activities were transferred from [redacted] to your firm's Insurgentes facility in Tijuana, Mexico. In total, bioburden was not monitored in seventeen (17) production lots that were produced between February 2004, through June 2004.

2. Failure to establish procedures for purchasing control data that clearly describe or reference specified requirements for purchased or otherwise received product and services, as required by 21 CFR 820.50(b).

   Failure to establish and maintain procedures for acceptance of incoming product, as required by 21 CFR 820.80(b).

For example, your firm failed to establish a procedure for purchasing control data that identifies the specifications for [redacted] used in the final cleaning step on the [redacted]. In addition, your firm failed to establish an acceptance procedure to ensure that specified requirements for the [redacted] are met.

3. Failure to review and evaluate a manufacturing process and perform revalidation, where appropriate, when changes or process deviations occur, as required by 21 CFR 820.75(c).

   For example, your firm did not qualify major manufacturing equipment during installation qualification (IQ) as part of manufacturing process validation activities when the CapnoProbe sensor manufacturing process was transferred from [redacted] to Nellcor (Tijuana, Mexico). This equipment includes the [redacted] the [redacted], and the [redacted] used to control the bioburden on the CapnoProbe sensors. Our investigator observed that these equipment were qualified after your firm initiated the recall of the CapnoProbe sensor on August 24, 2004, but before initiation of our inspection on November 01, 2004.

This letter is not intended to be an all-inclusive list of violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

If you fail to take prompt corrective action, FDA may take regulatory action without further notice to you. Given the serious nature of these violations of the Act, FDA may detain your product without physical examination upon entry into the United States under section 801(a) of the Act (21 U.S.C. 381(a)), until the violations described in this letter are corrected, because the product appears to be adulterated within the meaning of section 501(h) of the Act (21 U.S.C. 351(h)). In addition, United States federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of government contracts.

In order to remove your product from detention, you should provide a written response to this Warning Letter as described below and correct the violations described in this letter. We will notify you if your response is adequate, and we may need to re-inspect your facility to verify that the appropriate corrections have been made.

We received a response from David Olson, Vice President, Regulatory Affairs, dated November 24, 2004, concerning our investigator's observations noted on the FDA 483. We

have reviewed your response and have concluded that it is inadequate for the following reasons:

1. Your firm acknowledges that the CapnoProbe sensor design Risk Assessment (hazard analysis) was incomplete because it did not include all potential device failure modes associated with biological hazards. Further, your firm acknowledged that it failed to select the appropriate level of monitoring and control for process parameters and component and device characteristics. However, no corrective action and no evidence of implementation of the correction has been submitted. Please submit the corrective actions taken by your firm and evidence of the implementation of these corrections for FDA's review.

2. The procedures for purchasing control data that clearly describe or reference specified requirements for received product and acceptance of incoming product, i.e., [redacted] and other manufacturing process products were not provided. Please submit these procedures for FDA's review.

3. Please provide a rationale for the Manufacturing Process Transfer Validation Plan as to which equipment could be fully verified and which required validation. This should include an explanation as to why the [redacted] were not initially qualified as part of the original manufacturing process validation activity, but were subsequently qualified after the CapnoProbe sensor recall on August 24, 2004.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter, of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include all documentation of the corrective action you have taken. If you plan to make any corrections in the future, include those plans with your response to this letter as well. If the documentation is not in English, please provide a translation to facilitate our review.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement B, Orthopedics, Physical Medicine, and Anesthesiology Devices Branch (OPMAD), 2094 Gaither Road, Rockville, Maryland 20850 USA, to the attention of William MacFarland, Chief OPMAD.

If you need help in understanding the contents of this letter, please contact William MacFarland at the above address or at (240) 276-0120 or FAX (240) 276-0129.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health